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Attorneys for Defendants
Sun Pharmaceutical Industries Ltd. and
Sun Pharmaceutical Advanced Research Centre

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

)
ALTANA PHARMA AG and WYETH,)
)
Plaintiffs,)
)
v.) Civil Action No.: 05-1966 (JLL)
)
SUN PHARMACEUTICAL INDUSTRIES)
LTD. and SUN PHARMACEUTICAL)
ADVANCED RESEARCH CENTRE)
)
)
Defendants.)
)

)

**SUN PHARMACEUTICAL INDUSTRIES LTD. AND SUN
PHARMACEUTICAL ADVANCED RESEARCH CENTRE'S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendants Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Advanced Research Centre (hereinafter collectively "Sun"), by their attorneys, for their Answer respond as follows:

THE PARTIES

1. Sun is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 1 of the Complaint and therefore denies them.
2. Sun is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 2 of the Complaint and therefore, denies them.
3. Paragraph 3 is not a factual or legal allegation and requires no response.
4. Admitted.
5. Sun denies the allegations of ¶ 5 of the Complaint except admits that Sun Pharmaceutical Research Centre (the correct name for the entity) is a division of Sun Pharmaceutical Industries, Ltd., and is located at NIMA Compound, Near Pratham Enclave, Tandalja Road, Baroda 390020, India.
 6. Admitted.
 7. Paragraph 7 is not a factual or legal allegation and requires no response.
 8. Admitted.
 9. Sun admits that it markets pharmaceutical products in the United States, including in New Jersey. Sun denies ¶ 9 of the Complaint in all other respects.
10. Sun admits that it manufactures pharmaceutical products and bulk pharmaceuticals that are sold and used in the United States, including in New Jersey. Sun denies ¶ 10 of the Complaint in all other respects.
11. Sun admits that it has authorized Mr. Guttman to accept service of process on behalf of Sun and has consented to personal jurisdiction and venue in New Jersey. Sun denies ¶ 11 of the Complaint in all other respects.

12. Upon information and belief, Sun admits that New Drug Application No. 20-987 was approved by the United States Food & Drug Administration for 20 mg and 40 mg delayed-release tablets including the active ingredient pantoprazole sodium, and such tablets are prescribed for gastro-intestinal disorders associated with acid secretion. Upon information and belief, Sun admits that such tablets are promoted in the United States under the trade name "PROTONIX®." To the extent not admitted, Sun is without further information sufficient for a belief as to the truth or falsity of the remaining allegations found in ¶ 12 of the Complaint and, therefore denies them.

13. Sun admits that United States Patent No. 4,758,579 ("the '579 patent") issued on July 19, 1988, and that it purports to disclose certain compounds allegedly useful for inhibiting gastric acid secretion. Sun is without information sufficient to form a belief as to the truth or falsity of the remaining allegations found in ¶ 13 of the Complaint and therefore denies them.

14. Sun is without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 14 of the Complaint and, therefore, denies them.

15. Sun admits that a copy of the '579 patent was attached as Exhibit A to the Complaint.

16. Admitted.

17. Admitted.

18. Admitted.

19. Sun is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 19 of the Complaint and therefore denies them.

20. Sun is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 20 of the Complaint and therefore denies them.

21. Sun denies that it infringes any valid and enforceable claim of the '579 patent.

22. Denied.

23. Denied, except that Sun admits it was aware of the existence of the '579 patent.

24. Denied.

25. Denied.

26. Denied.

PRAYER FOR RELIEF

27. In response to Plaintiffs' prayer for relief in the Complaint:

a. Sun denies that Plaintiffs are entitled to the relief requested in ¶ 27(a) of the Prayer for Relief.

b. Sun denies that Plaintiffs are entitled to the relief requested in ¶ 27(b) of the Prayer for Relief.

c. Sun denies that Plaintiffs are entitled to the relief requested in ¶ 27(c) of the Prayer for Relief.

d. Sun denies that Plaintiffs are entitled to the relief requested in ¶ 27(d) of the Prayer for Relief.

e. Sun denies that Plaintiffs are entitled to the relief requested in 27(e) of the Prayer for Relief.

f. Sun denies that Plaintiffs are entitled to the relief requested in ¶ 27(f) of the Prayer for Relief.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

28. Upon information and belief, the claims of the '579 patent are invalid, void and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 132, 135, 256 and 287.

SECOND AFFIRMATIVE DEFENSE

29. Sun will not infringe any valid and enforceable claim of the '579 patent under 35 U.S.C. § 271.

THIRD AFFIRMATIVE DEFENSE

30. The claims of the '579 patent which purport to cover pantoprazole are invalid under the judicially created doctrine of obviousness type double patenting.

FOURTH AFFIRMATIVE DEFENSE

31. Plaintiffs fail to state a valid claim for willful infringement.

COUNTERCLAIMS

Sun, for its counterclaims against Plaintiffs, alleges as follows:

THE PARTIES

1. Sun Pharmaceutical Industries Ltd. is a public limited liability company incorporated and existing under the laws of the State of India, and has a principal place of business located at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai 400059, Maharashtra, India.

2. Upon information and belief, Altana is a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

3. Upon information and belief, Wyeth is a Delaware corporation with its headquarters located at Five Giralda Farms, Madison, New Jersey 07940.

JURISDICTION

4. This is a declaratory judgment action under 28 U.S.C. §§ 2201 and 2202. The counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and under the Food, Drug and Cosmetic Act of the United States, 21 U.S.C. § 355(j). Jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 21 U.S.C. § 355(j).

5. Altana Pharma AG (hereinafter “Altana”) and Wyeth have filed a patent infringement lawsuit against Sun.

FACTUAL BACKGROUND

6. Upon information and belief, Altana is currently the owner of the United States Letters Patent Nos. 4,758,579 (the ‘579 patent).

7. Upon information and belief, Wyeth Pharmaceuticals, Inc., a wholly-owned subsidiary of Wyeth, holds an improved New Drug Application from the FDA for pantoprazole sodium delayed-release tablets.

8. Sun has filed ANDA No. 77-058 for approval to market a pantoprazole sodium delayed-release tablet, eq. 20 mg and 40 mg base in the United States.

9. Sun sent a notice letter related to ANDA No. 77-058 pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to Wyeth and Altana on March 1, 2005, which notice letters, upon

information and belief, were received by Altana on or about March 8, 2005, and by Wyeth on or about March 4, 2005, respectively. Sun also sent earlier notice letters to both Altana and Wyeth.

10. On or about April 13, 2005, Altana and Wyeth filed or caused to be filed a Complaint for patent infringement which alleges that Sun infringes the '579 patent.

COUNT I

INVALIDITY OF THE '579 PATENT

11. The allegations of ¶¶ 1-10 of Sun's Counterclaims are repeated, realleged, and incorporated herein by reference.

12. Upon information and belief, the claims of the '579 patent are invalid, void and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 132, 135, 256 and 287.

13. The claims of the '579 patent are invalid under the judicially created doctrine of obviousness type double patenting.

COUNT II

NON-INFRINGEMENT OF THE '579 PATENT

14. The allegations of ¶¶ 1-13 of Sun's Counterclaims are repeated, realleged and incorporated herein by reference.

15. Sun will not infringe any valid and enforceable claim of the '579 patent under 35 U.S.C. § 271.

PRAYER FOR RELIEF

WHEREFORE, Sun prays that the Court enter:

A. A declaratory judgment that the '579 patent is invalid;

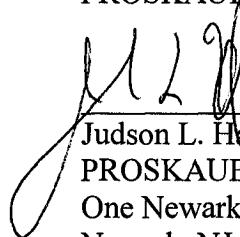
B. A declaratory judgment that Sun will not infringe any valid and enforceable claim of the '579 patent under 35 U.S.C. § 271;

C. An Order enjoining and restraining Altana and Wyeth and their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them from further charges of infringement or acts of enforcement based on the '579 patent against Sun, its actual and prospective customers, suppliers, clinical investigators, and anyone in privity with Sun; and

D. An Order awarding Sun such other further relief as the Court deems just and equitable.

Dated: May 5, 2005

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